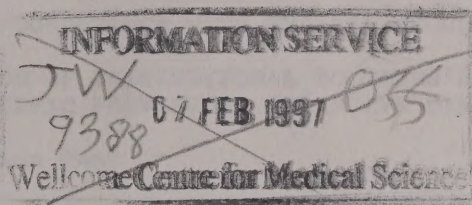


Rockville MD 20857



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INSTITUTIONAL COMPLIANCE REVIEWS

The Office of Research Integrity (ORI) has recently added formal institutional compliance reviews to its oversight of inquiries and investigations. This function, previously handled informally by the Division of Research Investigations within ORI, has been placed in the ORI Division of Policy and Education (DPE).

Initially, these reviews have concentrated on cases where problems of compliance have come to light during ORI's oversight of institutional inquiries and investigations. In addition, investigations of alleged retaliation against whistleblowers are now part of the compliance review process.

Each of these institutional compliance reviews contains two major components.

The first component compares the institution's policies and procedures with the provisions of the relevant PHS regulation (*Federal Register*, 42 CFR Part 50). The institutional policies and procedures are examined for adherence to these specific provisions.

The second component examines the actual process used by the institution in an inquiry and/or investigation of research misconduct to determine if the process utilized was consistent with the institution's own policies and procedures and the PHS regulation.

At the conclusion of each review, a final report is prepared assessing the institution's compliance with both the PHS regulation and its own administrative process. This report is provided to officials at the institution reviewed in draft form for comment before it is finalized. Any recommendation for corrective actions is provided to the institution along with the final report of the compliance review.

The attached document indicates the issues that are examined during each of the two parts of the compliance review.



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COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation

Regulation Text

Revised 6/30/94

INSTITUTION: _____

EFFECTIVE DATE OF POLICIES AND PROCEDURES: _____

APPLIES TO : _____

[faculty, staff, graduate/undergraduate students, employees, contractors,
visiting scholars, all members of academic community at institution, etc.]

OTHER RELEVANT POLICIES AND PROCEDURES:

Reviewer's Comments:

Section 102 - Definitions

"Inquiry"

means information gathering and initial factfinding to
determine whether an allegation of apparent instance of
misconduct warrants an investigation.

Complete Institutional Definition:

"Investigation"

means the formal examination and evaluation of all relevant
facts to determine if misconduct had occurred.

Complete Institutional Definition:

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation	Regulation Text
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"Misconduct" or "Misconduct in Science"

means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

Complete Institutional Definition:

Section 103(d) - Inquiries, Investigations, and Reporting - Specific Requirements. Each applicant's policies and procedures must provide for:

103(d) (1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on the report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

Institutional Citation (reference/text):

103(d) (2) Protecting to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

Institutional Citation (reference/text):

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation

Regulation Text

103(d) (3)

Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

Institutional Citation (reference/text):

103(d) (6)

Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry and shall upon request be provided to authorized HHS personnel.

Institutional Citation (reference/text):

103(d) (7)

Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

Institutional Citation (reference/text):

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation	Regulation Text
103 (d) (8)	<p>Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation.</p> <p>Institutional Citation (reference/text):</p>
103 (d) (9)	<p>Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.</p> <p>Institutional Citation (reference/text):</p>
103 (d) (10)	<p>Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, [ORI] who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.</p> <p>Institutional Citation (reference/text):</p>
103 (d) (11)	<p>Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.</p> <p>Institutional Citation (reference/text):</p>

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation	Regulation Text
103(d) (12)	<p>Keeping the [ORI] appraised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.</p> <p>Institutional Citation (reference/text):</p>
103(d) (13)	<p>Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.</p> <p>Institutional Citation (reference/text):</p>
103(d) (14)	<p>Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.</p> <p>Institutional Citation (reference/text):</p>
103(d) (15)	<p>Notifying the [ORI] of the final outcome of the investigation.</p> <p>Institutional Citation (reference/text):</p>

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation	Regulation Text
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Section 104(a) - Reporting to the ORI

104(a) (1)	An institution's decision to initiate an investigation must be reported in writing to the Director, [ORI] on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS applications or grant number(s) involved.
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Institutional Citation (reference/text):

104(a) (2)	An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making the report available for comment by the subjects of the investigation and submitting the report to the [ORI]. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.
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Institutional Citation (reference/text):

104(a) (3)	Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under 50.103(d) a report of such planned termination, including a description of the reasons for such termination, shall be made to [ORI], which will then decide whether further investigation should be undertaken.
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Institutional Citation (reference/text):

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation

Regulation Text

104(a) (4)

The final report submitted to the [ORI] must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as description of any sanctions taken by the institution.

Institutional Citation (reference/text):

104(a) (5)

If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the [ORI] a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the [ORI]. If satisfactory progress is not made in the institution's investigation, the [ORI] may undertake an investigation of its own.

Institutional Citation (reference/text):

COMPLIANCE WITH FEDERAL REGULATION

COMPARISON OF INSTITUTIONAL POLICIES AND PROCEDURES
WITH SPECIFIC PROVISIONS OF 42 CFR PART 50 SUBPART A

Citation

Regulation Text

Section 104(b) - The institution is responsible for notifying the [ORI] if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

104(b) (1)

There is an immediate health hazard involved:

Institutional Citation (reference/text):

104(b) (2)

There is an immediate need to protect Federal funds or equipment:

Institutional Citation (reference/text):

104(b) (3)

There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her coinvestigators and associates, if any:

Institutional Citation (reference/text):

104(b) (4)

It is probable that the alleged incident is going to be reported publicly.

Institutional Citation (reference/text):

104(b) (5)

There is a reasonable indication of possible criminal violation. In that instance, the institution must inform [ORI] within 24 hours of obtaining that information. [ORI] will immediately notify the Office of the Inspector General.

Institutional Citation (reference/text):

Revised 6/30/94

Case Evaluation:
Comparison of the Institutional Process
With Applicable Policies and Procedures

The following document is used to determine whether the administrative process used by an institution for a review of alleged misconduct is consistent with the Federal Regulation (42 CFR, Part 50, Subpart A) and the institution's own policies and procedures for handling allegations of misconduct in science.

Allegations

1. Explicit procedures for reporting allegations

Describe and assess procedures included within institutional policies and procedures for reporting allegations, and evaluate compliance with those procedures:

2. Immediate response to each allegation (103.c.3; 103.d.1)

Describe institutional process for responding to allegations, and evaluate institutional adherence to process:

Elements Specific to both Inquiries and/or Investigations

3. Selection of necessary and appropriate expertise for inquiries and/or investigations (103.d.8)

How many members were named to the inquiry and/or investigation panels? Was appropriate expertise available?

<u>Name</u>	<u>Expertise</u>
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4. Prevention of real or apparent conflicts of interest in inquiries and/or investigations (103.d.9)

Were steps taken to prevent real or apparent conflicts of interest in the inquiry and/or investigation?

Describe:

5. Protect the confidentiality of complainant and respondent in an inquiry and/or investigation (103.d.3)

Were steps taken to protect the confidentiality of complainant and respondent? (Y/N) If yes, describe steps:

6. Provide an opportunity to complainant and respondent to comment on allegations and findings of inquiry (103.d.3)

Were respondents given an opportunity to comment on the allegations during the inquiry (Y/N)?

If no, why not?

If yes, were their comments included as part of the file (Y/N)?

7. Provide an opportunity to complainant and respondent to comment on allegations and findings of investigation (103.d.3)

Were respondents given an opportunity to comment on the allegations during the investigation (Y/N)?

If no, why not?

If yes, were their comments included as part of the file (Y/N)?

8. Notification to ORI within 24 hours of obtaining a reasonable indication of possible criminal violations (103.d.5)

If there were reasonable indications of criminal violations, was ORI notified within 24 hours of this development (Y/N)?

If yes, date:

9. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under 50.103d, a report of such planned termination, including a description of the reasons for such termination, shall be made to ORI (104.a.3)

Was there a termination of an inquiry and/or an investigation (Y/N):

If so, was this action(s) properly reported to the ORI (Y/N)?

Date Reported:

Reason for Termination:

Elements Specific to Inquiries

10. Complete inquiry including report within 60 calendar days of its initiation (103.d.1)

Date of Receipt of Allegation:

Date of Appointment of Inquiry Panel:

Date of Inquiry Report:

Request for Extension (Y/N); if Yes, date:

11. Documentation for extending inquiry beyond 60 calendar days (103.d.1)

If inquiry extended, describe:

12. Content of inquiry report includes evidence reviewed, interview summaries, and conclusions of the inquiry (103.d.1)

Evidence Reviewed:

Interviewees:

Interviews Summarized (Y/N):

Conclusions:

13. Inquiry report given to the respondent(s): comments by respondent made part of the inquiry record (103.d.1)

Inquiry report given to respondent (Y/N):

Respondent's comments attached to report (Y/N):

14. Maintain detailed documentation of an inquiry for at least three years and provide to authorized HHS personnel upon request (103.d.6)

Evidence to the contrary:

Elements Specific to Investigations

15. Initiate investigation within 30 days of date of inquiry report that recommends an investigation (103.d.7)

Date investigation initiated:

Compare with date of inquiry report; is it within 30 days? (Y/N)

16. Providing notification to ORI that an investigation is required. The notification should be sent to ORI on or before the date the investigation begins. Such notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegations, and the PHS application or grant number(s) involved (103.d.4; 104.a.1)

Date ORI notified of investigation:

Compare with date investigation initiated; is date ORI notified prior to date investigation began? (Y/N)

Notification includes:

Respondent(s):

Allegation(s):

PHS research involved:

17. Investigations include examination of all documentation including relevant research data and proposals, publications, correspondence, and memoranda of telephone calls (103.d.7)

Description:

18. Interviews should be conducted with all involved individuals; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file (103.d.7)

<u>Interviewees</u>	<u>Date</u>	<u>Summaries Reviewed (Y/N)</u>
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Were summaries included as part of investigatory file (Y/N)?

19. Making the report of the investigation available to the respondent(s) for comment (104.a.2)

Made available (Y/N):

If Yes, date:

20. Complainants should be provided with those portions of the report that address their role and opinions in the investigation (104.a.2).

Made available (Y/N):

If Yes, date:

Was rebuttal provided (Y/N):

If so, describe:

21. Complete investigation and submit report to ORI within 120 calendar days of appointment of investigative committee (104.a.2)

Date of Appointment of Investigative Cmtee:

Date Investigative Rpt submitted to ORI:

Compliance with section 104.a.2 (Y/N):

22. Submit to the OSI a request for an extension if unable to complete the investigation in 120 days. The extension

request should include an explanation for the delay, an interim report on the progress to date, an outline of what remains to be done, and an estimated date of completion (104.a.5)

Date:

Explanation of Delay:

Summary of Interim Report:

Summary of Outline of what remains to be done:

Estimated date of completion:

(Repeat five elements noted above for each instance; attach additional sheets as necessary)

23. Final report to ORI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution (104.a.4)

Describe; attach additional sheets as necessary.

24. Was there any evidence of mistreatment of the complainant, respondent, or witnesses?

25. Promptly advising ORI of any developments during the course of the investigation which disclose facts that may affect current or potential DHHS funding for institution

investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest (103.d.12)

Description, as appropriate:

26. Maintain detailed documentation to substantiate an investigation's findings for at least three years after PHS has accepted the final report

Description, as appropriate:

Administrative Actions

27. Taking appropriate interim administrative actions to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out (103.d.11)

<u>Date of Action</u>	<u>Description of Action</u>	<u>ORI Notified</u>
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28. Making efforts to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed (103.d.13)

Describe any actions taken:

29. Protecting, to the maximum extent possible, the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct (103.d.13)

Describe any actions taken:

30. Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated (103.d.14)

Describe any actions taken:

31. An institution has informed its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures (103.c.2)

Describe any evidence supporting compliance with this provision:

